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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,851	09/09/1999	EDWARD M SELLERS	064658.0129	8120

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BROBECK, PHLEGER & HARRISON, LLP
ATTN: INTELLECTUAL PROPERTY DEPARTMENT
1333 H STREET, N.W. SUITE 800
WASHINGTON, DC 20005

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/09/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/214,851

Applicant(s)

SELLERS ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001 .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,10,14,15,24,31-33 and 37 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-20 and 25-29 is/are allowed.
- 6) ☒ Claim(s) 1-4,7-9,11-13,16,21-23,34-36 and 38 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____ .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
- 4) ☒ Interview Summary (PTO-413) Paper No(s) Z .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: NOTICE TO COMPLY.....

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DETAILED ACTION

The following is responsive to Applicant's election received April 27, 2001.

Claims 1-38 are currently pending.

Election/Restriction

1. Applicant's election with traverse of Group I with a further election of species to methoxsalen in Paper No. 7 is acknowledged. Applicant has not specifically pointed out the supposed errors with the restriction requirement. Therefore, the restriction is maintained for reasons given in the office action mailed March 27, 2001.

The requirement is still deemed proper and is therefore made FINAL.

No prior art was found for using the elected species "methoxsalen" in a method for treating a condition requiring regulation of nicotine metabolism as required by claims 11-13, 16 and 38. Therefore, the search was expanded to "pilocarpine". Please see paragraph 13 below.

Claims 5, 6, 10, 14, 15, 24, 31-33, 37 are withdrawn from consideration as being drawn to non-elected subject matter.

Priority

2. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

Sequence Listing

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This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given THREE MONTHS from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. ✓

Information Disclosure Statement

Applicant's Information Disclosure Statement received Sep. 9, 1999 has been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. ✓

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Claim Objections

4. Claim 30 is objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, claim 30 has not been further treated on the merits.

5. Claim 38 is objected to because of the following informalities: in claim 38, line 4, after "capable of", the phrase "regulating inhibition" should be deleted and replaced with --inhibiting the metabolism-- as this is consistent with the terminology used in the specification at page 19, lines 20-21. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. Claims 34-36 provide for the use of a substance which selectively inhibits CYP2A6, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 34-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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For purposes of advancing prosecution, the claims will be interpreted as methods of making a medicant.

7. Claims 11-13, 16, 21-23, 38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 11 recites the limitation "the subject" in line 2. There is insufficient antecedent basis for this limitation in the claim. ✓

9. Claim 38 recites the limitation "the subject" in line 2. There is insufficient antecedent basis for this limitation in the claim. ✓

10. Claim 21 is vague and indefinite due to the use of the term "and/or" at line 3. The scope of the claimed subject matter is unclear because one of ordinary skill in the art would not be able to readily determine what constitutes the claimed pharmaceutical composition. As currently presented with the term "and/or", claim 21 may comprise (1) a substance which inhibits CYP2A6, or (2) a substance which inhibits CYP2B6 or (3) a pharmaceutically acceptable carrier, diluent or excipient (option (3) results in a pharmaceutical composition with no active ingredient). It is not clear if Applicant intends to claim a pharmaceutical composition comprising a substance which inhibits CYP2A6 and a substance which inhibits CYP2B6 and/or a pharmaceutically acceptable excipient OR a composition comprising a substance which inhibits CYP2A6 or a substance which inhibits CYP2B6 and/or a pharmaceutically acceptable excipient. ✓

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The metes and bounds of the patent protection desired is not readily ascertainable to one of ordinary skill in the art.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2, 3, 4, 7-9, 21, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Maenpaa et al.

Maenpaa et al. disclose studies to determine the effect of methoxsalen on coumarin 7-hydroxylation in humans by administering 45 mg of a composition comprising methoxsalen to five human subjects. Results show that methoxsalen inhibited coumarin metabolism effectively in every subject. Please see the abstract; page 1364, first paragraph under **RESULTS**.

The claims are anticipated by Maenpaa et al. because Maenpaa et al. teach administration of an identical agent, i.e. methoxsalen, to a host using Applicant's claimed method steps.

Accordingly, regulation of nicotine metabolism would be inherent.

13. Claims 11, 12, 13, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Garnitskij et al., SU 1803032.(based upon an oral translation of the reference).

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Garnitskij et al. disclose a method for treating abstinence syndrome in tobacco dependence, the method comprising administering an effective amount of (0.2-0.5 ml) a 1% solution of pilocarpine HCL to the tongue of a human. Please see the abstract submitted herewith.

14. Claims 7-9, 21-23, 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Mays et al.

Mays et al. disclose a method of studying the effect of methoxsalen on caffeine metabolism by treating nonsmoking volunteers with psoriasis with an oral dose of 1.2 mg/kg methoxsalen. The methoxsalen was provided by Elder Pharmaceuticals. Please see the abstract; page 622,

Material and Methods, Chemicals.

Concerning the use claims 34-36 which are being examined as a method for preparing a medicament for regulation of nicotine metabolism, the Examiner respectfully submits that the ultimate intended use of the medicament i.e. "for the regulation of nicotine metabolism" is not germane to the issue of patentability of the method of making claim. Please refer to MPEP 2111.02, page 2100-46, where it is stated,

"In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no significance to the structure and process of making.)".

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In the instant case, the Examiner respectfully submits that the intended use of regulating nicotine metabolism to cotinine is of no significance to the process of preparing the medicament.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garnitskij, supra in view of Modi et al., 5,653,987.

Garnitskij as applied above.

Garnitskij does not disclose adding an effective amount of a substance which “inhibits” the metabolism of the pilocarpine; however, the Examiner refers to Modi et al., which discloses that combining antioxidants, such as ascorbic acid (vitamin C), with pharmaceutically active agents to prevent degradation of said agents is recognized by those skilled in the art. Please see col. 3, lines 33-36; claim 6. Furthermore, Modi et al. disclose that protease inhibitors may be added to a pharmaceutical composition to inhibit degradation of the pharmaceutical agent by enzymes. Please see col. 3, lines 46-48.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine pilocarpine with an antioxidant and/or an enzyme inhibitor, with the expectation of avoiding unwanted degradation of pilocarpine, thereby delivering greater amounts of pilocarpine to the patient suffering from tobacco dependence.

Allowable Subject Matter

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Claims 17-20 and claims 25-30 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed methods.

Conclusion

Claims 1-4, 7-9, 11-13, 16, 21-23, 34-36, 38 are rejected.

Claim 30 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

Sep. 4, 2002


Cybille Delacroix-Muirheid
Patent Examiner Group 1600

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ 7. Other: _____

Applicant must provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

- For Rules Interpretation, call (703) 308-1123
- For CRF submission help, call (703) 308-4212
- For PatentIn software help, call (703) 308-6856

Please return a copy of this notice with your response.